DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 8, 2015

LZR7 Incorporated
% Ms. M. Joyce Heinrich
Texas Applied Biomedical Services
12101 Cullen Boulevard, Suite A
Houston, Texas 77047

Re: K150466
Trade/Device Name: ZX2 Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: May 8, 2015
Received: May 11, 2015

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150466

Device Name
ZX2 Laser System

Indications for Use *(Describe)*
The ZX2 Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Exhibit 2. 510(k) Summary (as per 21 CFR 807.92)

I. GENERAL INFORMATION

Device Generic Name: Infrared Laser System

Trade Name: ZX2 LASER SYSTEM

Device Classification: Class II, Performance Standards – 21CFR Part 890.5500 – Infrared Lamp

Product Code: ILY

Sponsor Name and Address:
LZR 7, Inc.
1980 Broadway
Placerville, CA

Applicant Name and Address:
M. Joyce Heinrich
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510(k) Number: K150466

II. Device Description

The ZX2 Laser System is a non-invasive, low energy, infrared therapeutic medical laser. The ZX2 Laser incorporates an AC Control Unit and a variety of hand-held laser probes. The Control Unit has two (2) completely independent probe outputs which allow use of the device by two operators at once and/or treatment using two probes at once.

The Control Unit houses the power supply, electronics and user interface panel. The Control Unit is connected to a suitable grounded outlet. The Control Unit is equipped with a key which when inserted into the switch the Unit can be activated. The ZX2 has an emergency stop button that, when pressed, will deactivate the device. The device houses a split screen panel on the face of the control unit and dual control buttons for use with two independent probes.

The hand-held probes that are optional with the ZX2 Laser System include:

1. 750 mW Deep Probe – 808 nm GaAlAs Semiconductor laser
2. 1.5 W Deep Probe – 808 nm GaAlAs Semiconductor laser
3. 6.1 W Multi Probe – 808 nm GaAlAs Semiconductor laser / 658 nm Ga Aa InP
4. SP4 Probe – 904 nm Ga As Semiconductor Laser Pulsed

The above laser probes incorporate laser diode/s at 658nm, 808nm and 904nm diodes, classifying it under 21 CFR 890.5500, ILY infrared lamp for adjunctive use in pain therapy.

III. Indications for Use

The ZX2 Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

IV. Predicate Devices

The ZX2 Laser is substantially equivalent to other infrared therapeutic devices that are currently in commercial distribution. The primary predicate is Apollo Physical Therapy Products International's Apollo IR Heat Lamp System (K060134).

V. Summary of the Technical Characteristics of the ZX2 Laser as Related to the Referenced Predicate Device.

The ZX2 Laser System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared laser diodes, and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

VI. Electrical and Safety Testing

Electrical safety and functional performance testing were conducted on the ZX2 Laser demonstrating that the device is compliant with FDA recognized consensus standards. These standards include the following international standards:

1. EN 60601-1: 2006 Ed. 3 - Medical Electrical Equipment, Part 1, General Requirements for Safety
2. EN 60601-1-2:2012 - Medical Electrical Equipment, General Requirement for Safety. Electromagnetic Compatibility
3. EN 60601-2-22:1996 – Medical Laser Equipment

VII. Non-clinical Testing

THERAPEUTIC HEAT TEMPERATURE DATA

The ZX2 Laser System is capable of achieving therapeutic heat temperature range of 40 - 45 degrees centigrade as accepted by the FDA. An increase in topical heating of the tissue level by at least 5^{o} centigrade was reached within 3 - 4 minute(s) demonstrated in the bench testing that was conducted on the treatment head. The therapeutic temperature range was maintained until the device was turned off. The achieved therapeutic temperature range was maintained for the 10 minute testing time. The spot size for the devices used in the Temperature vs. Time studies was 9.35 cm2.

The use of light energy to generate heat for therapeutic use has been well documented and is generally accepted alternative treatment modality for the temporary relief of pain and tissue repair.

The ZX2 Laser System emits infrared light energy to provide topical heating for the purpose of elevating tissue temperature to safely increase local blood flow and circulation where heat is applied. These devices have been used in Europe for over 10 years demonstrating clinical efficacy and benefit with no reported adverse effects.

The average ambient temperature at the beginning of the testing was approximately 19 degrees centigrade. The temperature versus time testing was performed on various body areas: i.e., knee, shoulder, neck and low back and on three (3) different individuals. The data were analyzed and an average of the temperature for each body area is summarized.

The pre-exposed topical skin temperature ranged from 31 to 35 degrees centigrade. The topical temperature during exposure following brief stabilization time ranged from 27 to 33 degrees centigrade. These data demonstrate the ZX2 Laser System meets the generally accepted topical temperature range for therapeutic heat of 40 – 45 degrees centigrade during the recommended treatment time of 10 minutes. Representative results of the Temperature vs. Time tests are summarized in Tables 1 - 3 below. To ensure the topical skin temperature does not exceed the maximum acceptable therapeutic heat temperature, the ZX2 incorporates a heat sensor that has an automatic shut off once the device exceeds a temperature of 44 degrees centigrade.

Table 1.

Sex: M Age: 52 Ethnicity: White

Room Temperature: start = 19 ^{0}C

Room Temperature: end = 19 ^{0}C

Device: 6.1W Multi - Average Power: 6100mW

Warming time: 2 minutes

Low Back		Knee	
Time (min)	Temp (^{0}C)	Time (min)	Temp (^{0}C)
initial	*35*	*initial*	*32*
1	33	1	29
2	36	2	33
3	40	3	36
4	41	4	39
5	43	5	40
6	45	6	42
7	45	7	44
8	46	8	44
9	46	9	45
10	47	10	46
Mean (Active):		Mean (Active):	

Table 2.

Sex: F Age: 44 Ethnicity: White

Room Temperature: start = 21 ^{0}C

Room Temperature: end = 21 ^{0}C

Device: 6,1W Multi - Average Power: 6100mW

Warming time: 2 minutes

Neck		Knee	
Time (min)	Temp (^{0}C)	Time (min)	Temp (^{0}C)
initial	*34*	*initial*	*31*
1	33	1	27
2	35	2	31
3	39	3	35
4	41	4	40
5	42	5	41
6	44	6	42
7	45	7	43
8	45	8	44
9	46	9	44
10	46	10	45
Mean (Active):		Mean (Active):	

Table 3.

Sex: M Age: 41 Ethnicity: White

Room Temperature: start = 16 ^{0}C

Room Temperature: end = 17 ^{0}C

Device: 6,1W Multi - Average Power: 6100mW

Warming time: 2 minutes

Shoulder		Low Back	
Time (min)	Temp (^{0}C)	Time (min)	Temp (^{0}C)
initial	*32*	*initial*	*31*
1	31	1	31
2	35	2	34
3	38	3	38
4	41	4	40
5	42	5	42
6	43	6	44
7	45	7	45
8	44	8	45
9	45	9	46
10	46	10	46
Mean (Active):		Mean (Active):	

VIII. Conclusions

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device may have the same intended use and different technological characteristics if they can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regards its safety and effectiveness as compared to the predicate device.

The ZX2 Laser has the same intended uses, technical, functional and performance characteristics as the predicate device listed above. The ZX2 Laser is designed to comply with applicable performance standards promulgated by Federal Food and Drug Administration.